Title: Randomized Controlled Trial of ADHD Portal-Integrated Behavioral

Reward Program Intervention

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ABSTRACT:

Though the most effective treatment for children with Attention Deficit Hyperactivity Disorder (ADHD) consists of combined medication and behavioral strategies, the vast majority of children with ADHD are treated with medication only. While effective, medication primarily targets ADHD symptoms and typically has little to no impact on ADHD-related areas of functional impairment such as academic underachievement, impaired social relationships, and disrupted family functioning. One reason for the low rates of behavioral treatment is that primary care pediatricians, not mental health professionals, are responsible for treating the vast majority of children with ADHD. We have developed, tested, and are beginning to disseminate web-based software (www.mehealth for ADHD.com) that has been shown in randomized clinical trials to improve the quality of ADHD medication care delivered by pediatricians. However, the current software functionality is limited entirely to medication management. The goal of the proposed study is to test the integration of behavioral tools into the evidence-based mehealth for ADHD.com software in order to improve access to behavioral treatment strategies, and ultimately improve outcomes for children with ADHD. The automated algorithms and decision rules we developed for creating and monitoring the behavioral tools will ensure that behavioral treatments like daily report cards and token economies are delivered in a manner that is consistent with the evidence-base. We will conduct a randomized control trial to assess whether those with access to the behavioral tools exhibit the following: 1) higher rates of behavioral treatment; 2) better integrity of behavioral treatments when they are used; 3) less functional impairment; and 4) higher satisfaction with ADHD treatment than families in the control group. By continuing to expand the functionality of the mehealth for ADHD.com software, we are increasing families' access to evidence-based care. This is especially critical for rural and underserved communities who have no or limited access to evidence-based mental health services. Moreover, by putting these behavioral tools in the hands of parents, teachers, and pediatricians, we are making it more likely that children will receive a high quality of care that includes both medication management and behavioral strategies, thereby improving the overall treatment outcomes of children with ADHD.

PURPOSE OF STUDY:

The primary goal of the proposed project is to test the integration of behavioral tools into the evidence-based mehealth for ADHD.com software in order to improve the access to and the integrity of evidence-based behavioral treatment strategies for children with ADHD.

BACKGROUND:

Statement of the problem

The Center for Disease Control and Prevention's (CDC's) national survey on ADHD diagnosis and treatment patterns in the United States documented that 11% (6.4 million children) of children ages 4 – 17 years had been diagnosed with ADHD at some point in their lives, with 8.8% of all children currently diagnosed with ADHD(Susanna N Visser et al., 2014). Children with ADHD experience significant impairments across multiple domains of functioning, including educational, interpersonal, and family functioning(DuPaul & Stoner, 2014; Efron et al., 2014; Wehmeier, Schacht, & Barkley, 2010; Wymbs et al., 2008). Fortunately, evidence-based treatments for children with ADHD exist(Steven W Evans, Owens, Mautone, DuPaul, & Power, 2014). Pharmacological treatment is by far the most commonly used treatment for ADHD(S. N. Visser et al., 2015; Susanna N Visser et al., 2014). Pharmacological treatments clearly produce marked improvement in ADHD symptoms (e.g., improved attention, reduced hyperactivity)³⁶ (Pliszka, 2007). However, ADHD symptom improvements do not translate into

overall improvements in functional impairment(Currie, Stabile, & Jones, 2014; J.N. Epstein et al., 2010; O'Connor, Garner, Peugh, Simon, & Epstein, 2015).

The other treatment strategy included in evidence-based treatment guidelines is behavioral treatment. Behavioral treatments for ADHD specifically target areas of functional impairment such as noncompliance, social functioning, homework completion and organization skills(Chronis, Jones, & Raggi, 2006; DuPaul, Eckert, & Vilardo, 2012; Steven W Evans, Owens, & Bunford, 2013; Pfiffner, Villodas, Kaiser, Rooney, & McBurnett, 2013; Storer, Evans, & Langberg, 2014) and have been shown to be quite effective (i.e., effect sizes on functional impairment approach 0.61 [Cohen's d](Vannest, Davis, Davis, Mason, & Burke, 2010); see Fabiano et al. (Gregory A Fabiano et al., 2009) for a meta-analytic review). Given that pharmacological treatment primarily improves ADHD symptoms and behavioral treatments improve impairments, it is perhaps not surprising that combining these two treatment modalities is the most effective treatment option and is universally recommended (Chronis et al., 2006; Daly et al., 2007; Education, 2004; Pediatrics, 2011; Psychiatry, 2007). Combined treatment results in larger improvements than either modality alone (Conners et al., 2001). Further, it has been documented that when children are receiving behavioral treatment, lower doses of medication can be used(Gregory A Fabiano et al., 2007; W. E. Pelham et al., 2014; Vitiello et al., 2001). Also, parents and teachers view behavioral treatments as highly acceptable (Corkum, Bessey, McGonnell, & Dorbeck, 2015; Gage & Wilson, 2000; Liu, Robin, Brenner, & Eastman, 1991; Monastra, 2005; Power, Hess, & Bennett, 1995; Wilson & Jennings, 1996). Despite the acceptability and efficacy of behavioral treatments, either alone or in combination with medication, less than 25% of children with ADHD receive behavioral treatments (J.N. Epstein et al., 2014; Gellad et al., 2014). Hence, most children with ADHD are not receiving a critical modality of ADHD treatment - behavioral treatment - and thus remain functionally impaired.

Why don't children with ADHD receive evidence-based behavioral treatments?

Despite being regarded as a mental health disorder, the majority of children with ADHD are evaluated and treated by primary care physicians - generally pediatricians - rather than by mental health specialists (Bernal, 2003; Zito et al., 1999). Most pediatricians accept the evaluation and treatment of children with ADHD as being a core job responsibility(Stein et al., 2008). However, pediatricians are inclined to provide medication to children with ADHD but very rarely provide, facilitate, or refer children/families for behavioral treatments(J.N. Epstein et al., 2014; Gellad et al., 2014).

Fortunately, the reasons that the vast majority of children with ADHD treated by community-based pediatricians do not receive behavioral treatments are fairly well understood. First, pediatricians consistently report that they do not have the time or knowledge to deliver behavioral treatments to their patients with ADHD(S. M. Horwitz et al., 2007). Second, most communities lack access to effective and affordable behavioral treatment. For example, only 33% of pediatricians believe that behavioral treatments are readily accessible in their communities(Rushton, Fant, & Clark, 2004). This belief is supported by recent data from the Health Resources and Services Administration which concluded that more than four-fifths of US counties do not have enough mental health professionals to accommodate the need for mental health services(Services, 2012). Further, pediatricians are concerned that if they refer families, the behavioral treatments available will be low quality, unaffordable(Fiks, Hughes, Gafen, Guevara, & Barg, 2011) and will require long wait times(S. M. Horwitz et al., 2007). Third, parents of children with ADHD share these concerns, with 53% of parents reporting system barriers (e.g., insurance reimbursement) to receiving ADHD behavioral treatment(Bussing, Zima, Gary, & Garvan, 2003; P. L. Owens et al., 2002).

How can the accessibility and integrity of behavioral treatments be addressed?

It is clear innovative methods are needed to 1) *increase the accessibility* of behavioral treatments to children with ADHD as well as to 2) *improve the integrity* of treatment delivery of behavioral treatments. Realizing that pediatricians are likely to remain the primary mental health providers, many have argued that the best approach to improving mental health outcomes is to support primary care physicians in their delivery of mental health services(J. Geller & Muus, 1997; J. M. Geller, 1999). One promising method for providing this support is through the use of technology. In fact, the US government has promoted the use of technology to address health care disparities through both American Recovery and Reinvestment Act funding initiatives and mandates within the recent Patient Protection and Affordable Care Act which specifically proposes the meaningful use of technology to improve health care for all citizens (Public Law 111-148; March 23, 2010).

In response to these governmental mandates, technologically-based and telehealth interventions have increased rapidly across the US (Medicine, 2012). While many of these online interventions offer some form of professional support, many are self-quided and involve merely interaction with a web-based interface. Though early technological intervention research demonstrated the advantage of supported types vs. self-guided web-based interventions(Richards & Richardson, 2012), several recent studies using more interactive interfaces have demonstrated that self-quided technological-interfaces are as effective as supported technological interventions (Berger, Hammerli, Gubser, Andersson, & Caspar, 2011; Dear et al., 2015; Furmark et al., 2009; Leykin, Muñoz, Contreras, & Latham, 2014). Moreover, some of these web-based self-guided interventions produce similar treatment effect sizes to clinician-delivered interventions (Carlbring, Westling, Ljungstrand, Ekselius, & Andersson, 2001; Proudfoot et al., 2004), and have similar levels of satisfaction as traditional face-to-face interventions(Spence, Holmes, March, & Lipp, 2006). To date, effective self-quided web-based cognitive-behavioral interventions have been developed and demonstrated to be efficacious for several disorders, which similar to ADHD have established evidence-based treatments. These include interventions for social phobia(Berger, Caspar, et al., 2011), OCD(Wootton, Dear, Johnston, Terides, & Titov, 2014), depression(Berger, Hammerli, et al., 2011) and insomnia(Lancee, van den Bout, van Straten, & Spoormaker, 2013).

The development of behavioral interventions for children with ADHD (e.g., daily report cards, token economies) which involve the development and refinement of appropriate behavioral goals, defining the monitoring schedule, monitoring performance, and deriving effective rewards can all be facilitated through web-based algorithms and interfaces. Specifically, we propose to develop web-based software that allows multiple users (e.g., parents, teachers) to work collaboratively to develop behavioral goals, monitoring schedules, and reward plans. Program routines, called wizards, will guide parents and teachers though a series of customized steps to develop and implement behavioral treatments for home and/or school. A software wizard or setup assistant is a type of user interface that presents a sequence of dialog boxes that lead the user through a series of steps towards goal completion. Wizards can prompt parents and teachers to identify and prioritize behavioral targets, aid in the collection of baseline data on behavioral targets, and assist with the creation of rewards and reward schedules. Moreover, a web-based platform allows for online data capture and graphing of children's performance, providing a simple way for parents to track progress towards behavioral performance goals. Also, the wizard will be programmed to ensure that behavioral targets, monitoring schedules, and rewards are realistic and evidence-based. Further, the wizard can provide suggestions for improving the integrity of the intervention (e.g., frequency of monitoring, saliency of reward, level needed for goal attainment), when adequate progress is not being made. A major advantage of such online behavioral tools is that they remove the need for a pediatrician to implement the behavioral treatments and do not require referral to a mental health professional when access is limited due to cost, transportation issues, scheduling difficulties, or a shortage of mental health providers.

STUDY DESIGN:

The primary goal of the proposed project is to develop and test the integration of behavioral tools into the evidence-based myadhdportal.com software in order to improve the access to and the integrity of evidence-based behavioral treatment strategies for children with ADHD. To accomplish this objective, we propose the following specific aim:

- 1) Conduct a cluster-randomized controlled trial in community pediatric settings to test whether integration of the behavioral tools into the myADHDportal.com software:
 - a) increases access to and rates of behavioral treatment:
 - b) facilitates better integrity of behavioral interventions when implemented:
 - c) improves functional impairment in children with ADHD; and
 - d) generates higher satisfaction with ADHD care.

SELECTION AND RECRUITMENT OF PARTICIPANTS

Up to 200 parents will be recruited and randomized. Parents of children in the K-6 grade range was selected because the vast majority of research establishing the efficacy of behavioral treatments was conducted with elementary school age children. For medicated patients, we will require that they be on a stable medication/dosage for 1 month prior to their participation in the study to reduce the possibility that medication or dosing changes occur during the period of study enrollment. By reducing medication/dosing changes, we can more accurately attribute child outcomes to implementation of behavioral strategies. Even with this specification, medication/dosage changes will occur. We will assess for medication/dosage changes throughout the study and statistically control for these in analyses.

To recruit participants, we will ask local pediatricians that are currently using the mehealth for ADHD portal to send out correspondence to their patients' parents that are registered on the mehealth for ADHD portal inviting them to participate in the study. The pediatricians we have identified to date that we will use for this research protocol have more than 1,500 patients registered on the mehealth for ADHD portal. The correspondence from the physician's office to their patient's parents will either occur via phone, mail, email, or using the messaging system within the mehealth for ADHD portal. It will be up to the physician's office which method of correspondence to utilize for contacting their patients' parents. If contacted by phone, office staff will use a phone script. If parent expresses willingness to be contacted, office staff will gather the parent's contact information over the phone and provide the parent's contact information to the research team. Email, mail, and messaging system correspondence will contain a link to a REDCap form that will allow parents to enter their contact information if they wish to be contacted by research staff. As needed, we may also recruit additional pediatrician's which use the mehealth for ADHD portal.

Participants will also be recruited from a patients previously seen at Cincinnati Children's Hospital Medical Center (CCHMC) Division of Behavioral Medicine and Clinical Psychology (BMCP) who are in the right age range and have a diagnosis of ADHD. Potentially eligible families will be sent a letter indicating that they were identified because of having been seen previously at BMCP along with a "do not contact" postcard. The letter will include a written link to a REDCap form that will allow parents to send their contact information to study staff. Contact information for study staff will also be provided to allow parents to call or email study staff directly. Families not returning the "opt out" postcards within 2 weeks of mailing may be called by research staff to share more about the study and invite participation.

A research assistant will contact the parent to provide them with additional information about the study. If the parent is interested in participating, the parent will be asked several questions to ensure that the parent meets the study's inclusion criteria. Specifically, the parent

will be asked whether their child: 1) is in grades K-6; 2) has been diagnosed with ADHD; 3) if currently being prescribed ADHD medication, ensuring they have been on a stable medication/dosage for 1 month; and 4) is still experiencing ADHD-related impairment at school as evidenced by a score of 3 or higher on any item related to academics or school on the parent or teacher Impairment Rating Scale. Parents must also have access to a computer or smartphone to participate. In order to characterize the sample and to ensure that the sample is representative, parents will also be asked their Medicaid status and race/ethnicity information. Research staff will also explain to the parent that if their child is randomized to receive the intervention, they will be encouraged to use the behavioral tools during the next year. If the parent states that they are not interested or unwilling to use the tools, they will not be eligible to participate.

PROCESS OF OBTAINING CONSENT

In order to obtain physician consent, the PI or study staff will review and have physicians sign the consent form at the initial meeting.

If the parent was recruited from a participating pediatrician's practice and meets criteria, the research assistant will review the consent and discuss the study in detail with the parent. If the participant continues to be interested in participating, a study staff member will request specific information (i.e., parent's first and last name, date of birth, zip code, and e-mail address) in order to enroll them in the e-consent software. This information on all eligible participants will be entered/uploaded into the web-based consent management application hosted at CCHMC. An email notification will be sent to the email address provided by the parent. All email notifications sent for this study will not contain any PHI. The email will contain a link which will allow the parent to view the e-consent web site. This link will be unique to the participant and will have a pre-defined expiration date. Parents will log into the consent application and the password will be their current ZIP code. They will then be presented with the consent form. After reading through the form (i.e., scrolling to the bottom), they will have an opportunity to check a box stating that they agree to provide their consent. There will also be fields for full name. Once they have typed their full name, they will be able to submit. Included in the email and the econsent document will be contact information for parents to message a study staff member if they have questions. Parents can also provide a phone number via the e-consent application if they wish for study staff to call them about their questions. If parents have questions, they will be asked to come back to the application after those questions have been resolved. After a participant has submitted their consent, a link will appear giving them the option to print a copy or save the consent form.

If the parent was recruited because their child was a patient at BMCP and meets criteria, the research assistant will review the consent and discuss the study in detail with the parent. If the participant continues to be interested in participating, a study staff member will request specific information (i.e., parent's first and last name and e-mail address) in order to send the parent a link to a REDCap consent form. After reading through the form (i.e., scrolling to the bottom and selecting "Yes" to consenting), they will have an opportunity to submit their consenting signature. All email notifications sent for this study will not contain any PHI. The email will contain a link which will allow the parent to view the REDCap form and study consent form. This link will be unique to the participant. Parents will view the REDCap application and will be presented with the consent form.

As children are not the targeted research participants and all data will be obtained from parents only, we do not intend to obtain children's assent for this study.

In addition to the parent's participation, we will also recruit one of the child's teachers to participate in the study. If participant is consented with less than a month remaining in the current school year, the child's teacher for the subsequent school year will be contacted about

participating at the beginning of the next school year. To contact teachers, research staff will send the parent a letter that the parent can deliver to the child's teacher telling them about the research and asking them for permission to be contacted by research staff. In this letter, there will be a REDCap survey link allowing them to provide their contact information (i.e. first and last name, email address, phone number) as well as the first and last name of the student that is requesting their participation in the study. Two methods will be used to inform teachers about the study. Either a member of the research staff will call the teacher and describe the research study to the teacher using a phone script for teachers. Or a member of the research staff will email teachers an email script describing the study and a link to their REDCap survey. The phone script and email text explicitly ask teachers to complete forms about the child's behavior at school. If a teacher is contacted prior to randomization and is not willing to use the behavioral features or complete forms about the child's behavior, the family will not be eligible to participate in the study.

STUDY PROCEDURES

PI or study staff will meet with each pediatrician to go over study procedures and obtain informed consent. After this meeting, study staff will perform a brief orientation with pediatricians of the software and their role in the study.

Once informed consent is collected from the parent, the parent will be emailed a link to complete baseline measures using REDCap survey. The parent will also be called to complete a phone interview regarding service use assessment. The teacher will be emailed a link to a REDCap survey to complete the teacher-completed forms. Once parent and teacher (for students whose parents consent prior to 1 month before the end of the school year) have completed the forms, the parent will be randomly assigned to either receive 1) immediate access to the integrated behavioral tools on the mehealth for ADHD portal, or 2) wait-list control group whereby they will receive access to the integrated behavioral tools on the mehealth for ADHD portal after 1 year. In order to control for the types of patient populations and settings across the two groups, randomization will occur within each pediatrician. That is, an equal number of families of each pediatrician will be assigned to the intervention and control groups. Randomizing in this manner should ensure equal representation of Medicaid status and race/ethnicity across the two groups. During the brief orientation with pediatricians, they will be made aware of the integrated behavioral tools intervention that their families may have access.

Both intervention and control families will continue to have access to the mehealth for ADHD software. However, the intervention group will have access to integrated behavioral tools immediately (see description below) while the control group will not receive access to the behavioral tools for 1-year.

Families enrolled in this research study will have access to the mehealth for ADHD.com software with the randomized features for at least a 1-year period. At 6-, and 12-months post-baseline, research assistants will contact parents and teachers and administer measures related to behavioral tool implementation, patient outcomes (i.e., functional impairment), and consumer satisfaction. If the 6- or 12-month post-baseline time point will fall during the summer months, we will collect an additional set of questionnaires from the parent and teacher at the end of the child's academic year in order to capture how well the child is doing in school. These surveys will be administered preferably using online surveys (REDCap) but research assistants will administer these surveys by phone if parents are not responsive to online administration or indicate that they prefer phone administration.

At the end of the study, physicians will be asked to fill out a Pediatrician Consumer Satisfaction Survey that will ask how satisfied they were with the software.

Integrated Behavioral Tools

Evidence-based behavioral strategies employ operant procedures (i.e., rewarding desired behaviors) in order to increase the chances that the desired behavior will be emitted again in the future. For example, one of the most widely used behavioral treatments is a Daily Report Card (DRC). The DRC provides children with ADHD with specific, immediate, and frequent feedback to facilitate behavior change. A DRC typically consists of up to three specifically defined target behaviors that a teacher monitors and tracks during the school day. The DRC is sent home to parents each day after school where rewards/consequences are applied based upon the child's performance. The efficacy of DRCs has been evaluated for children with ADHD as part of large multi-modal interventions (e.g., MTA Study(MTA Cooperative Group, 1999)), as a stand-alone intervention(J. S. Owens et al., 2012), and as implemented through IEPs(Gregory A Fabiano et al., 2010). DRCs have been shown to improve parent-teacher communication and to improve the behavioral and academic functioning of children with ADHD(Gregory A Fabiano et al., 2010; J. S. Owens et al., 2012). Other evidence-based behavioral interventions such as a token economies are effective(Reitman, Hupp, O'Callaghan, Gulley, & Northup) (also see(Antshel & Barkley, 2008; W. E. Pelham, Jr. & Fabiano, 2008) for reviews) and utilize the same principles of behavior change, but instead focus on behavior in the home setting.

Description of integrated behavioral tools

1. Orientation to behavioral tools

Within the existing mehealth for ADHD.com software, each registered patient has a record page which includes a section for treatment. As described above, there was previously only functionality to initiate or track medication treatment. We have added a link that pediatricians can click to recommend the use of behavioral tools to a family. Once clicked, the parent will receive an email message via the mehealth for ADHD.com software's communication system that 1) indicates that their pediatrician is recommending the use of this tool for their child; 2) describes the behavioral tool feature; and 3) provides them with a link to initiate the behavioral tool online within the parent-accessible module of the mehealth for ADHD.com software. A similar link exists on the parent page that allows a parent to initiate the behavioral tool for their child. Also, we included a link on the teacher page that allows a teacher to recommend the behavioral tool to parents. Whether initiated by the pediatrician, parent, or teacher, the behavioral tool wizard begins with a description of the behavioral tool and a delineation of the required steps to create and implement the tool. A critical feature to orienting parents to the behavioral tools is motivating and engaging them to initiate the behavioral tool with their child. We have relied heavily on our stakeholders to provide feedback regarding best methods for engaging parents in this process. Indeed, in developing the current mehealth for ADHD.com software, we relied heavily on pediatrician stakeholders to guide us regarding methods for engaging pediatricians in the use of the mehealth for ADHD.com software. As a result, the mehealth for ADHD.com homepage now employs video testimonials from pediatricians as well as a brief informational video regarding functionality of the mehealth for ADHD.com software to motivate pediatricians to sign up to use the portal. We explored similar methods with our stakeholders for motivating parents to utilize the behavioral tools.

2. Identify the child's behaviors that require targeting

The next step is for parents and/or teachers to identify the child's behaviors they would like to target with behavioral treatment. Parents or teachers can select from a list of potential target behaviors or they can customize their own behaviors to target. If the parent has selected a school-based goal, the automated wizard sends a message to the teacher 1) describing the behavioral tool that the parent is in the process of creating; 2) delineating the steps that the teacher will need to take to create and implement this tool at school; and 3) providing a link to allow the teacher to engage with the automated wizard to engage with the tool creation process. Similar to engaging parents to initiate the behavioral tool, we have also explored methods for

engaging teachers in the creation and use of the behavioral tool with their student. After teachers log on to the mehealth for ADHD.com software, teachers see the full list of school-based behaviors identified as targets and are prompted to prioritize this list of behaviors.

3. Collect baseline data about target behaviors

Once target behaviors have been identified, a behavioral grid (see Figure 3) is generated that allows behaviors to be tracked daily over the course of a single week to establish a baseline frequency for that behavior. The behavioral grid can be maintained online and is able to be accessed via computer or using a mobile interface on a smartphone or it may be printed out and completed on paper and then entered daily into the online grid by either the parent or teacher at their convenience.

Daily Report Card

Child's Name:

Target Behaviors

8.45-9:45

8.46-9:45

8.46-9:45

Math

Social Studies

Recess

Keeps hands to himself yes No Yes No

4. Finalize target behavior goals

After the baseline week's behavioral data is collected/entered, computerized algorithms within the wizard will derive SMART (Specific, Measurable, Attainable, Relevant, and Time-limited) behavioral goals. Behavioral goals must be achievable during the initial weeks of the

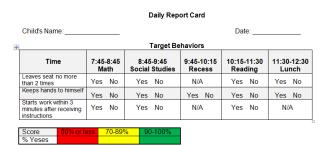


Figure 3: Sample behavioral grid for recording performance on target behaviors

behavioral intervention in order for children to experience success and become motivated by their receipt of the rewards. Thus initial SMART behavioral goals are set to require a defined, realistic, percent improvement from baseline for each behavior.

5. Create plan for monitoring child's target behaviors

After SMART behavioral goals are generated by the wizard, a behavioral grid is generated along with a suggested monitoring schedule. Monitoring intervals are the time points each day when parents and/or teachers provide the student with feedback regarding their performance on the behavioral goals for the past interval. After parents/ teachers have suggested modifications and agreed upon a final monitoring schedule, the behavioral grid will be finalized and behavioral monitoring will begin. As during baseline data collection, parents and teachers can record the child's performance directly into the online system or they can print out the behavioral grid, record on the printed version, and enter the data online at their convenience. Parents and teachers are also able to choose if they would like to receive reminders by text or email to complete ratings.

6. Reward child for performance

Right before monitoring begins, the automated wizard prompts the family to develop a daily reward system. An effective daily reward system includes multiple reward levels. We used green, yellow, and red levels based on children meeting defined thresholds for each level. Again, we collaborated with our stakeholders to develop these thresholds. Parents and children derive a list of daily rewards that will occur at each level if that behavioral target is met. The online wizard helps the parent and child come up with a suggested daily reward hierarchy (e.g., green level = 1 hour of video games; yellow level = ½ hour of video games; red level = no video games) and a weekly reward. Once the behavioral monitoring begins, parents will receive daily and weekly email or text communications from the wizard alerting them to the daily rewards earned by their child.

7. Modify behavioral goals over time

Behavioral performance over time is charted using annotated behavioral run charts (see Figure 4) which will be continuously monitored by computerized algorithms. Parents are able to view these charts from within the software. In addition, teachers are able to view progress on school-based behaviors when they log on. If algorithms detect that a behavioral goal is being consistently met (e.g., child earns green level for 5 consecutive days), the parent and teacher are notified via messaging that performance goals have been met and need to be modified. Algorithms will then suggest a modification for the next performance goal. For example, if the

initial goal of raising your hand before speaking with less than 6 violations per day is being met consistently, the suggested next performance goal might be "interrupting the teacher less than 3 times per day." Once a child consistently meets a performance goal which eliminates that behavior (e.g., 0 class disruptions), the automated wizard will suggest another behavior to target based on previously identified behaviors. In addition, each time a new behavioral goal is selected, families are prompted to update the monitoring schedule and schedule of rewards if necessary.

Interface with pediatrician

While the behavioral tools are designed in such a way to eliminate the need for pediatricians to manage the provision of these behavioral tools, it is important for pediatricians to be involved in monitoring the child's progress. Pediatricians have the ability to review graphing of behavioral goals which have been modified to not only show medication and dosage changes, but also annotate the initiation of behavioral treatment as well as modifications to the behavioral treatment. This allows pediatricians to track any improvements or deterioration in behavior and functional impairment as a result of behavioral treatment.

<u>Measures</u>: The table below provides information about the measures and timeline for administration. Parent measures will take about 30 minutes to complete and teacher measures will take about 10 minutes to complete.

Measure	Completed by	Baseline	End of school year*	6-month post	12-month post
Services Use Assessment	Parent	Х	X	Х	X
Impairment Rating Scale (IRS)	Parent, Teacher	X	Х	Х	X
Consumer Satisfaction Questionnaire	Parent, Teacher, Pediatrician		Х	Х	X
Demographics Questionnaire	Parent	X			
Parental Motivation Inventory	Parent	Х			
Adult ADHD Self-Report	Parent	X			
ADHD Knowledge and Opinion	Parent	Х			

^{*}This time-point will only be collected if the 6- or 12-month timepoint falls during the summer months.

a. <u>Services Use Assessment:</u> This phone interview will be administered to parents at all assessment points to capture children's ADHD service use across mental health, primary care, school, and community settings. Data from this interview will be used to determine if behavioral treatments were implemented and whether mental health professionals were involved in setting up and monitoring its use (access to behavioral treatments). For each behavioral intervention, the Service Use Assessment will include detailed questions about the estimated percent of time that behavioral monitoring was

- completed, the estimated percent of time that rewards were provided, and examples of behavioral targets and rewards. Furthermore, for post-baseline assessments for children treated by intervention providers, we will be able to query the web portal for much of this information. Two clinical child psychologists, blinded to study condition but familiar with behavioral interventions, will code the behavioral targets on a 1-10 scale as being appropriately operationalized or not. Also, reward schedules will be coded on a similar 1-10 scale. Reliability of codings will be established and monitored.
- b. Impairment Rating Scale (IRS): The IRS consists of 4 items included on both the parent- and teacher-report versions, including peer relations, academic progress, self-esteem items as well as an overall severity/impairment rating. The parent-report version also has items assessing sibling relations, parent—child relations, and impact of the child's behavior on the family, whereas the teacher-report version has items assessing teacher-child relations and classroom functioning. Items are rated on a scale ranging from 0 (no impairment) to 6 (extreme impairment). The IRS demonstrates excellent temporal stability and evidence of convergent and discriminant validity(G.A. Fabiano et al., 2006) and is sensitive to treatment effects(S. W. Evans, Langberg, Raggi, Allen, & Buvinger, 2005; S.W. Evans, Serpell, Schultz, & Pastor, 2007). Parents and teachers will complete their respective versions of this scale at baseline, follow-up (if the 6- or 12-month timepoint falls during the summer months), 6- and 12-months post-baseline.
- c. <u>Family/Teacher consumer satisfaction questionnaire</u>: Parents' and teachers' satisfaction will be assessed with a consumer satisfaction questionnaire that asks specifically about how satisfied they were with the myADHDportal.com software. Collected at baseline, follow-up (if the 6- or 12-month timepoint falls during the summer months) and 6- and 12-months post-baseline. At the conclusion of the study, we will invite some parents and teachers to participate in a post-study interview. Parents and teachers will be selected based on whether they provide negative feedback on the consumer satisfaction questionnaires. Those families will be contacted to query them further about their experience in order to explore ways to improve the software. Procedurally, we will email families asking them if they wish to participate in a follow-up phone call and ask them to contact us if interested.
- d. <u>Pediatrician consumer satisfaction questionnaire</u>: Pediatricians' satisfaction will be assessed at the end of their participation in the research study with a consumer satisfaction questionnaire that asks specifically about how satisfied they were with the myADHDportal.com software.
- e. <u>Demographics questionnaire</u>: We will ask parents to report on race/ethnicity, socioeconomic status, and level of education. Collected at baseline only.
- f. <u>Parental Motivation Inventory</u>: 25 item scale to assess parent motivation for treatment. The measure has good psychometric properties and has been shown to predict treatment adherence(Nock & Photos, 2006). Collected at baseline only.
- g. <u>Adult ADHD Self-Report Scale</u>: 18-item parent-completed measure to screen parents for ADHD. Collected at baseline assessment only.
- h. <u>ADHD Knowledge and Opinions Scale</u>: Used to query parents about their acceptability, feasibility, and perceived competence of treatment. Items are summed in each of these domains to provide estimates of these constructs(Bennett, Power, Rostain, & Carr, 1996). Collected at baseline only.

DURATION:

The entire project will take place over a 2-year time period.

DATA ANALYSIS:

Data management and methods to prevent and handling of missing data

Specific data structure routines will be utilized including double-entry bookkeeping and regular backup. Data discrepancies will be resolved by checking source documents to correct any inaccuracies. In order to ensure that missing data are not affecting the pattern of our results or affecting the representativeness of our sample, we will conduct a missing data attrition analysis to identify potentials for non-random or systematic attrition (MNAR) related to key independent and dependent variables. In cases of MNAR missing data, selection and pattern mixture models will be used to appropriately address non-random attrition.

Hypothesis testing

The primary set of analyses will be conducted following "intent to treat" principles (i.e., including all randomized subjects). Specifically, Hierarchical Linear Mixed Models (HLMM) will be used to evaluate the effectiveness of the interventions. We will use HLMM models to model individual variability in developmental trajectories in response to treatment and to model potential non-linear effectiveness(Kreft & DeLeuw, 1998). Further, HLMM models do not make assumptions requiring equal sample sizes, and allow for missing observations, subjects being measured at differing time points, as well as estimation of random subgroup specific effects. Thus, HLMM provides an efficient and powerful means of assessing time-invariant characteristics (e.g., gender or age) on mean changes in the dependent variable(Diggle, Liang, & Zeger, 1994).

Before conducting any analyses, comparability of patients across the intervention and control groups at baseline on a variety of variables will be assessed (e.g. gender, age, % of public insurance patients). These variables should be held equal via our randomization procedures. If they are not equal, these pediatrician variables will be used as covariates in the HLMM models.

<u>Hypothesis #1</u>: Children with ADHD who have access to the behavioral treatment tools on mehealth for ADHD.com will receive behavioral treatments at significantly higher rates as compared to children who do not have access to mehealth for ADHD.com-integrated behavioral tools.

<u>Hypothesis #2</u>: Children with ADHD who have access to the behavioral treatment tools on mehealth for ADHD.com will receive behavioral treatments of higher quality, as indicated by higher codings of the appropriateness of behavioral targets and rewards, compared to children who do not have access to mehealth for ADHD.com-integrated behavioral tools.

Analyses: A one-level (pediatricians) HLMM analysis will be conducted comparing intervention and control patients on rates and quality of behavioral treatment over time. Using data regarding use of behavioral treatment from baseline, 6-, and 12-month SCA-PI interviews, we will include Group (Intervention vs. Control) and Time (baseline, 6-, and 12-months) variables in the analyses. A Group x Time interaction term will indicate whether intervention effects are present.

<u>Hypothesis #3:</u> Children treated with access to the mehealth for ADHD.com enhanced with behavioral tools will have fewer areas of parent- and teacher-rated functional impairment than children treated for ADHD without access to the behavioral tools.

Analyses: The primary dependent measures for measurement of child outcomes will be the IRS total score as rated by parents and teachers. HLMM modeling will use a rater variable to allow parent and teacher ratings to be entered into the same model. These HLMM analyses will evaluate whether growth curves using baseline, 6-, and 12-month data are different across the two groups. For all analyses, our primary hypothesis predicting improved outcomes for children with access to the behavioral tools will be tested by examining the Group x Time interaction

effect. In order to control for additional treatments received by children in the intervention and control groups, we will add time-varying covariates indicating medication/dosing changes (for children in both groups) and institution of behavioral treatment (for children in the control group) to the HLMM models. Exploratory analyses will also assess for intervention effects across the separate IRS domains.

Hypothesis #4: Families treated for ADHD with access to the mehealth for ADHD.com enhanced with behavioral tools will have experience higher satisfaction with ADHD treatment compared to families treated for ADHD without access to the behavioral tools.

Analyses: The dependent measure for these analyses will be satisfaction summary scores from the consumer satisfaction measures. Similar to the child outcome analyses (Hypothesis #3), a HLMM analysis will be conducted using between-group comparisons of 6- and 12-month data from the randomized trial.

Exploratory moderator analyses: Possible moderators of treatment effects on rates of and integrity of behavioral treatment and patient outcomes include parental psychological distress, parental ADHD, and parental motivation for treatment. Each of these variables measured at baseline will be inserted into the hierarchical models as a main effect and as an interaction with time. Any interaction between the moderator variable and time would indicate that the moderator variable is impacting intervention efficacy.

Power analysis

The proposed study was powered to detect treatment effects on improving child outcomes since this is the ultimate goal of the proposed intervention. Effect size estimates for child outcomes were obtained from and from two randomized trials examining the efficacy of behavioral interventions (e.g., daily report cards) on functional impairment outcomes in children with ADHD (Gregory A Fabiano et al., 2010; J. S. Owens et al., 2012). Both of these studies report behavioral treatment effect sizes on functional impairment outcomes in the range of .40-.65 (Cohen's d). We used Optimal Design Software© (University of Michigan, 2005) to determine the appropriate sample size using the following assumptions: 1) $\alpha = 0.05$, 2) T = 3 repeated (baseline, 6 months, & 12 months) measurements, 3) repeated measures variance (σ^2) equal to 1, 4) family level variance ($\tau_{00}\&\tau_{11}$) equal to 1, and 4) a maximum 20% rate of longitudinal attrition (based on Epstein et al.(J.N. Epstein et al., 2007)). Based on these assumptions, we determined that power ≥ 0.80 could be achieved if we recruited up to 200 parents.

POTENTIAL BENEFITS:

Although we cannot guarantee a benefit to any individual participating parent, or teacher, the behavioral tools are evidence-based strategies with significant support from the research and clinical literature. Thus, families have the potential to benefit from state-of-the-art treatment (i.e., combined treatment with medication and behavioral interventions) which is recommended by the American Academy of Pediatrics for the care of ADHD (American Academy of Pediatrics, 2011). Benefits of the study outweigh any potential risks because our interventions are likely to improve care and outcomes for children who receive them.

POTENTIAL RISKS, DISCOMFORTS, INCONVENIENCES, AND PRECAUTIONS:

There is minimal risk to the participants in this study other than a potential for invasion of privacy. Because confidential information about study participants will be available to study staff, procedures to safeguard the confidentiality of this information are required. Several safeguards will be put in place. Study staff will have access to view participant data upon e-consent.

Database and system administrators in the Division of Biomedical Informatics at CCHMC will also have access to the database in order to perform quality assurance and system maintenance. The database of the consent management application is encrypted to prevent unauthorized data disclosure. The connection between the application front-end and the database and between the application front-end and the user's web browser is also encrypted. Using e-consent methods, if a participant declines to participate, the parent's records will be marked to denote his/her refusal. If a parent chooses not to consent, the data will no longer be used for research. Similarly, if a participant elects to withdraw consent at a later date, the participant's consent records will also be marked.

DATA MANAGEMENT AND SECURITY

All data collected on pediatricians, parents, and teachers will be assigned a unique code that will be linked to identifying information. The master coding sheet that will link the information will be kept in the study coordinator's office under lock and key. In addition to assuring confidentiality of the research data, it is also critical that the confidentiality of the family's clinical information is protected in mehealth for ADHD.com. The HIPAA regulations and their application to this product will be clearly defined to ensure compliance within their guidelines. Mehealth for ADHD.com was designed with a procedure for encrypting and storing the data in such a manner to only allow pediatricians to view identifiable data. This design employs a key-based encryption structure. This method does require extra security information to be maintained by the parties who are encrypting the data. For example, parties needing access to the data are assigned a "key" that is used to encrypt and decrypt the data in addition to a user ID. Such a key will be maintained by the PI and kept under lock and key. Implementation of additional methodologies to keep the confidential information off the server will be implemented including such methodology as ensuring the CCHMC server is secure (i.e., firewalled).

At the end of the study after analysis have been complete and publication of results completed, data will be anonymized. Any physical data will be kept in a locked file cabinet in the Center for ADHD. Any electronic data will be kept on a secure server with access limited to Center for ADHD employees. An IRB amendment or new proposal will be submitted prior to using the data for any future research.

PROTECTION OF VULNERABLE POPULATION:

The following procedures will be followed to avoid issues related to coercion or undue influence. Parents will be told that they can opt not to participate or answer any questions which they do not want to answer at any time. This will be re-iterated whenever necessary.

RISK/BENEFIT ANALYSIS:

The risks to participants are minimal and unlikely, largely stemming from the possibility of loss of confidentiality. We have instituted provisions to minimize this risk and will assure participants of the voluntariness of their participation and their right to withdraw participation at any time. We will also take appropriate steps to safeguard confidentiality. We would suggest that this study falls under the "Minimal Risk" category.

ALTERNATIVES:

Participation in the present study is completely voluntary. The alternative to participation in the study is to choose not participate in the study.

DATA SAFETY & MONITORING:

The randomized controlled trial will evaluate the effectiveness of the integration of behavioral tools into the mehealth for ADHD.com software compared to the wait list control group on rates of behavioral treatment, quality of behavioral treatment, children's functional impairment, and families' satisfaction with pediatrician-delivered ADHD care among up to 200 children with ADHD. Participants assigned to the intervention group will receive access to the mehealth for ADHD.com software with integrated behavioral tools. Participants assigned to the control condition will receive access to the regular mehealth for ADHD.com software and access to the integrated behavioral tools after 1 year. It is important to note here that the mehealth for ADHD.com software includes functionality whereby when a parent or teacher inputs rating scale information into the web portal during the course of monitoring treatment outcomes, computerized algorithms score and interpret this information and a report is produced. In addition, pediatricians are immediately alerted via email if there appears to be any exacerbation of side effects or deterioration in ADHD symptoms. Since (1) most of the risk in treating children with ADHD comes from pharmacological treatment which is not a part of the proposed study and (2) all participants are already using the mehealth for ADHD.com software that includes functionalities to automatically warn the pediatrician about side effects or behavioral deterioration, the safety risks of the study are minimal and there does not appear to be the need for an external monitoring board. Rather, Drs. Epstein (PI) and Brinkman (Co-I) will assume responsibility for the ongoing monitoring of the data and safety of the study, and will provide reports of this with annual renewal application to the IRB and annual progress report to the sponsor. Both are experts in ADHD research and have experience conducting communitybased research such as that proposed in this application. Dr. Brinkman has medical expertise related to pharmacotherapy of children with ADHD and Dr. Epstein has psychological expertise related to using behavioral treatments for use in treating children with ADHD to address studyrelated psychological issues. All research staff will complete education in the protection of human research subjects prior to study approval by the CCHMC IRB.

Drs. Epstein and Brinkman will continuously evaluate the project's performance, safety, treatment fidelity, and need to stop. Performance will be monitored by examining subject recruitment, comparison with targeted recruitment retention, protocol adherence, and quality of data collection procedures. This will primarily be accomplished in weekly staff meetings attended by Drs. Epstein and Brinkman as well as at the periodic meetings with the stakeholders. Any deviation in achieving recruitment targets will be reported to the program officer. In order to assure intervention fidelity, mehealth for ADHD.com will capture and report on data elements to characterize the use of behavioral tools. In order to assure the accuracy of data entry, data will be verified by double entering all data into a RedCap database. Inaccuracies will be addressed by double-checking the report forms.

COST OF PARTICIPATION:

There will be no costs to the subject for participating in this study.

PAYMENT FOR PARTICIPATION:

Materials collected from families will include questionnaires and interviews including questions related to family demographic characteristics, service use, and outcomes measures. These will all be administered via REDCap online or via phone at the time of enrollment, 6 months later, and finally 12 months later. An additional survey will be collected at the end of the school year if the 6- or 12-month assessment falls during the summer months. Families will be

reimbursed \$20 for their time completing each set of questionnaires at each time point. Teachers will be asked to complete questionnaires by online REDCap surveys or via phone about children's behavior at the time of study entry, 6 months later, and 12-months later. An additional survey will be collected at the end of the school year if the 6- or 12-month assessment falls during the summer months. Teachers will be reimbursed \$20 for their time completing these questionnaires at each time point. Parents and teachers will be reimbursed \$50 for their time participating in the post-study consumer satisfaction questionnaire feedback interview.

Each pediatric practice will be compensated \$80 for every 6 patients that consent to participate in the study up to a total of 30 patients. In addition, after 30 patients from the practice have consented to participate, the practice will be compensated an additional \$100. Participating pediatrician practices will also have access to the mehealth for ADHD web portal for 2 years at no charge.

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